

APR 10 2006

**Section 4**

**510(k) Summary**

(This Summary is submitted in accordance with 21 CFR Part 807, Section 807.92)

**Submitter's Name:** Boston Scientific Corporation

**Submitter's Address:** 2011 Stierlin Court  
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**Device Proprietary Name:** FilterWire EZ™ (2.25 mm – 3.5 mm) Embolic Protection System

**Device Common Name:** Embolic Protection Device

**Device Classification Name:** 21 CFR 870.1250, Percutaneous Catheter

**Device Class:** Class II

**Date Prepared:** July 15, 2005

**Identification of Predicate Devices:**

The Boston Scientific FilterWire EZ™ (2.25 mm – 3.5 mm) Embolic Protection System is substantially equivalent in design and intended use to the FilterWire EZ (3.5 mm – 5.5 mm) Embolic Protection System legally marketed under K032884 and to the Medtronic® PercuSurge GuardWire Plus® Temporary Occlusion and Aspiration System (K013913) indicated in 2.5 – 5.0 mm SVG vessel diameters.

**Device Description:**

The Boston Scientific FilterWire EZ (2.25 mm – 3.5 mm) Embolic Protection System is a temporary intra-vascular 0.014" guide wire filtration system that is placed distal to the vessel lesion to be treated by interventional procedures. The system consists of a Protection Wire (190 cm or 300 cm length), an EZ Delivery Sheath, an EZ Retrieval Sheath and accessories. The 190 cm long wire is compatible

with the Boston Scientific AddWire® Extension Wire (K970376 cleared June 6, 1997) for over-the-wire catheter exchanges.

The FilterWire EZ (2.25 mm – 3.5 mm) Protection Wire is delivered via the EZ Delivery Sheath. Once the Protection Wire is across the lesion, the filter bag is expanded in the artery lumen by removing the EZ Delivery Sheath. After treating the lesion, all interventional devices are removed, and the EZ Retrieval Sheath or EZ Bent Tip Retrieval Sheath is advanced to the proximal end of the filter and the filter loop is retracted into the EZ Retrieval Sheath, trapping any emboli caught during the procedure. The EZ Retrieval Sheath and EZ Protection Wire are then removed from the patient simultaneously.

### **Indications for Use:**

The FilterWire EZ (2.25 mm - 3.5 mm) Embolic Protection System represents a product line extension to the commercially available FilterWire EZ (3.5 mm – 5.5 mm) Embolic Protection System (K032884), so the indications for use statement is similar to that already cleared under K032884 except the reference to the diameter of the vessel at the site of filter loop placement which covers the range from 2.25 mm to 3.5 mm. Please note the indications statement includes a change in phrasing to emphasize the intended vessel diameter range for filter loop placement, and that range will be inclusive of the predicate and subject devices range. The proposed Indications for Use statement is provided below:

“The FilterWire EZ™ Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in coronary saphenous vein bypass grafts. The diameter of the vessel at the site of filter loop placement should be between 2.25 mm and 5.5 mm.

- The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral, carotid, or peripheral vasculature.
- The safety and effectiveness of the device as an embolic protection system has not been established in treating patients with acute myocardial infarction.
- The safety and effectiveness of the device as an embolic protection system has not been established in treating native coronaries.”

### **Summary of Technological Characteristics:**

The FilterWire EZ (2.25 mm – 3.5 mm) Embolic Protection System indicated for use in saphenous vein bypass grafts is equivalent to the FilterWire EZ (3.5 mm – 5.5 mm) Embolic Protection System cleared under K032884 and the Medtronic® PercuSurge GuardWire Plus® (GuardWire Plus\*) cleared under K013913 in that the intended use, principles of operation, design and materials are similar. The

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\* Also referred to as PercuSurge

following design attributes are the same or similar for the subject device and the identified predicate devices:

<b>Predicate Devices</b>		<b>Subject Device</b>
<b>FilterWire EZ (3.5 mm – 5.5 mm) System</b>	<b>Medtronic GuardWire Plus</b>	<b>FilterWire EZ (2.25 mm – 3.5 mm) System</b>
Single Operator Exchange delivery systems	Same	Same
Filter-based technology	Balloon-based technology	Filter-based technology
Nitinol® filter/basket component	Elastomeric Occlusion Balloon on Nitinol Hypotube	Nitinol® filter/basket component
Polyurethane filter membrane	Elastomeric Occlusion Balloon	Bionate™ polyurethane filter membrane
Compatibility with .014” guide wires	Same	Same
Compatibility with 6F guide catheters	Same	Same
Available in 2 lengths 190cm or 300 cm lengths	Same	Same
Radiopaque guide wire tips	Same	Same
Radiopaque markers on filter loop	Contrast/Heparinized saline mixture in balloon	Radiopaque markers on filter loop

#### **Performance Data:**

FilterWire EZ (2.25 mm – 3.5 mm) System in-vitro testing consisted of dimensional testing, tensile/torque testing and functional testing. Biocompatibility, packaging testing, product shelf life testing, functional testing in animal models and a clinical study in saphenous vein graft patients (G020229 - BLAZE II) have also been successfully conducted. In-vitro test results verified that the FilterWire EZ (2.25 mm – 3.5 mm) Embolic Protection System met all applicable product specifications and is deemed adequate for its intended use.

Results from the BLAZE II study (EmBoLic Protection TrAnsluminally with the FilterWire EZ DEvice in Saphenous Vein Grafts), designed to assess the FilterWire EZ (2.25 mm – 3.5 mm) Embolic Protection System during percutaneous treatment of saphenous vein graft stenosis in terms of 30-day MACE rates validated the safety and effectiveness of the FilterWire EZ (2.25 mm – 3.5 mm) System. These results were compared to the 30-day MACE results of a subset of GuardWire Plus patients from the FIRE Trial (K023691) (treated in the same vessel diameter range of 2.25 mm - 3.5 mm).

The BLAZE II study design was prospective, multi-center, and non-randomized. One-hundred thirty-one (131) registry patients, eight (8) roll-in patients and one (1) compassionate use patient were enrolled at 19 centers in this study. Clinical follow-up was performed 30 days post-procedure. The cumulative incidence of MACE at 30 days (primary endpoint) was 3.8% for the FilterWire EZ (2.25 mm – 3.5 mm) patients. The 30 day MACE results of the GuardWire Plus subset patients (treated in the same vessel diameter range of 2.25 mm - 3.5 mm) in the FIRE Trial was 12.4%.

The FilterWire EZ (2.25 mm - 3.5 mm) System demonstrated device performance with device success of 98.5%, clinical success of 94.7% and final TIMI 3 flow of 100%. Methods from the BLAZE II registry were analogous to the previously completed Randomized FIRE Trial (FilterWire EX / Medtronic GuardWire Plus) and the BLAZE study (FilterWire EZ) with respect to enrollment criteria and primary endpoint.

Due to the non-randomized nature of group membership, *adjusted* one-sided and two-sided confidence intervals of the treatment difference in 30-day MACE rate were also calculated as follows. For each individual, a propensity score for group membership (FilterWire EZ™ (2.25 mm – 3.5 mm), PercuSurge) was calculated using logistic regression, with “group” as the outcome and baseline and predictor variables as independent variables. Patients were then categorized into quintiles based on this propensity score. An estimate of the overall treatment difference (and its confidence interval) across all propensity score quintiles, adjusted for propensity score quintile, was calculated. By this method we obtain an adjusted difference between FilterWire EZ™ (2.25 mm - 3.5 mm) and PercuSurge on 30-day MACE rate of -4.4% with adjusted two-sided 95% CI of [-11.6%, 2.9%], and adjusted upper one-sided 95% CI of 1.8%, also supporting non-inferiority.

During conduct of the study, there were 40 BLAZE II patients who had at least one missing CK-MB result with the remaining CK-MB results being <3x normal range; there were 2 BLAZE II patients with missing CK-MB at all three time points (6-8, 12-16, and 18-24 hours post-procedure). To address this issue of missing CK-MB data, additional analysis on MACE was performed. In the primary analysis, these 42 patients were considered as not having non-Q wave MI since the majority of them had missing CK-MB due to being discharged early from the hospital because of no safety concerns. To estimate what the non-Q wave MI rate would have been for these patients had their missing CK-MB(s) been measured, the following analysis was performed. Data from FIRE, BLAZE and BLAZE II patients with non-missing CK-MB at all three time points (6-8, 12-16, and 18-24 hours post procedure) were used to statistically estimate, for each BLAZE II patient with missing CK-MB, the probability that at least one missing CK-MB was abnormal ( $\geq 3$ x normal range). The probabilities were then summed to obtain an estimate of the number of missing CK-MB patients who would have had an abnormal CK-MB and hence non Q-wave MI. The resulting estimate was that no more than 1 of these 42 patients would have had non Q-wave MI and, hence, MACE. The following table displays the results of a revised MACE analysis where one additional patient is included in the BLAZE II MACE incidence.

As can be seen, there is no marked change in results from the primary analysis; i.e., non-inferiority to GuardWire Plus is still achieved.

Table 6. Revised MACE analysis imputing 1 additional patient.

	<b>BLAZE II (N=131)</b>	<b>PercuSurge (N=169)*</b>	<b>Difference [95% C.I.]</b>	<b>Upper one-sided</b>
MACE (to 30 days)	4.6% (6/131)**	12.4% (21/169)	-7.8% [-13.9%, -1.6%]	-2.7%

\* Control group from FIRE trial with 2.25≤R VD≤3.5

\*\* Included additional MACE based on predicted values for missing CK-MB.

### Statement of Substantial Equivalence

Based on a comparison of intended use, results of in-vitro testing, in-vivo testing, biocompatibility, packaging, and clinical evaluation, Boston Scientific considers the FilterWire EZ (2.25 mm – 3.5 mm) Embolic Protection System substantially equivalent to the legally marketed FilterWire EZ (3.5 mm – 5.5 mm) Embolic Protection System (K032884) and the Medtronic® PercuSurge GuardWire Plus® Temporary Occlusion and Aspiration System (K013913).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 10 2006

Boston Scientific Corporation  
c/o Ms. Debbie McIntire  
Senior Regulatory Affairs Specialist  
2011 Stierlin Court  
Mountain View, CA 94043-4655

Re: K051984  
Trade/Device Name: FilterWire EZ<sup>TM</sup> Embolic Protection System, sizes 2.25 – 3.5mm  
Regulation Number: 21 CFR 870.2350  
Regulation Name: Distal Embolic Protection Guidewire  
Regulatory Class: Class II  
Product Code: NFA  
Dated: March 10, 2006  
Received: March 13, 2006

Dear Ms. McIntire:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Brady D. Zuckerman', with a long horizontal flourish extending to the right.

Brady D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



## Section 2

## Indications for Use

510(k) Number (if known) K051984

Device Name: FilterWire EZ™ (2.25 mm – 3.5 mm) Embolic Protection System

### Indications for Use:

The FilterWire EZ™ Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in coronary saphenous vein bypass grafts. The diameter of the vessel at the site of filter loop placement should be between 2.25 mm and 5.5 mm.

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- The safety and effectiveness of the device as an embolic protection system has not been established in treating native coronaries.

Prescription Use   X    
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use         
(Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number

K051984